REMARKS/ARGUMENTS

Claims 1, 5-7, 9, 12, 14, 18-19, and 105-108 are active in this case.

Support for the added phrase "assessing neurological function in said mammal" is found on page 39 of the application as originally filed.

No new matter is added.

The rejection of Claim 113, under 35 USC 112, second paragraph is no longer applicable.

Applicants thank the Examiner for the courtesy of meeting with their undersigned representative on April 16, 2009 to discuss the issues presented in the Action.

During this meeting, the written description rejection was discussed.

To the aspect of hemodynamically active compound and an agent that facilitates passage over the BBB, Claims 11 and 13 have been cancelled.

During the above-noted meeting, the rejection as it related to the G-CSF in the claims was discussed. It was explained that G-CSF is a well-known factor as described throughout the specification as previously discussed. In addition, reference was made to the publication of Aritomi et al (*Nature* 401:713-717 (1999), copy attached), which shows that before the present application was filed the structure of the G-CSF and its relationship with its receptor was well-known.

The Examiner indicated an appreciation for these facts but maintained the position relating to the aspects where the claims provided "one or more chemical substituents" and "fused to a second protein." While Applicants do not acquiesce to this position, based on the indication provided during the above-meeting that the phrases of "human G-CSF or a protein having at least 90% homology to SEQ ID NO:28" would not be subject to this written description rejection, Applicants have amended the claims to define such subject matter to expedite allowance of this case.

Reconsideration and withdrawal of the rejection is requested.

The discussion then turned to the rejections citing Heard with the newly cited Whalen et al publication.

On page 9 of the Action the Examiner states that because Whalen comments on Heard's study and that there could be a problem with the injured brain if/when treating the infections with G-CSF, the administration in Heard is inherently the same as the claims. Applicants explained that Whalen does not provide actual evidence that Heard's patients, those who received G-CSF, were necessarily TBI patients. Whalen does not resolve the primary deficiency of Heard that the patients to whom G-CSF was administered could not have been TBI patients but the other patients.

It was further discussed to amend the claims to provide a manner in which the TBI patients are treated and assessed, something not at all described or suggested by Heard. That is, as apparent from the claims submitted here, the claimed method includes assessing neurological function after the administration of G-CSF.

Heard teaches the treating of infection not TBI and therefore according to Heard, there would have been no reason to assess neurological function. In fact in view of the cited Whalen publications, one would have no reason and would be steered away from treating TBI and assessing neurological function. As acknowledged in the Action, Whalen opines that the treatment is likely detrimental to TBI patients situation.

Therefore, the claims cannot be anticipated by Heard, alone or with the cited P09919 and Whalen, nor would they have been obvious.

For similar reasons, the claims would not have been obvious in view of Heard with (A) Brines; (B) Deleuze; (C) Morita-Fukimura (D) Neupogen® product information; (E) Curran and Goa; and (F) MacVittie.

More specifically, Brines is relied upon to treat a combination treatment of TBI with erythropoietin (as an example of an additional hematopoietic factor). However, as Heard does not teach treating TBI but infections one would not have found guidance in Brines to supplement Heard's infection treatment protocol to treat the TBI.

Deleuze is relied upon to treat a combination treatment of TBI with TPA. However, as Heard does not teach treating TBI but infections one would not have found guidance in Deleuze to supplement Heard's infection treatment protocol to treat the TBI.

Morita-Fujimura is relied upon to treat a combination treatment of TBI with caspase inhibitors. However, as Heard does not teach treating TBI but infections one would not have found guidance in Morita-Fujimura to supplement Heard's infection treatment protocol to treat the TBI.

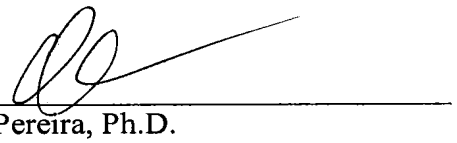
The remaining rejections similarly do not remedy the fact that Heard does not teach a method as is claimed where the treatment of TBI is effected by the administration of G-CSF and an assessment of those treated.

Reconsideration and withdrawal of all of the obviousness rejections applied under 35 USC 103(a) is requested.

A Notice of Allowance is also requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Daniel J. Pereira, Ph.D.
Attorney of Record
Registration No. 45,518

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 06/04)